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10/025,037	12/19/2001	Maurice O. Hevey	3099.12US02	5829

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,037	HEVEY, MAURICE O.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/19/04*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment filed 10/19/04.

Claims 1-6 are directed to a viscous carrier comprising vegetable oil, fish oil, and antioxidant.

Claims 7-18 are directed to a food supplement in a viscous carrier comprising vegetable oil, fish oil, antioxidant, and probiotic ingredients, which can be any agents recited in claim 13.

Claims 19-25 are directed to a method for delivering the carrier of claims 7-18.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Greenberg et al. US 3,745,023.

Greenberg discloses an appetite enhancing composition comprising 25-72 parts by weight of animal fat extracts, 25-72 parts by weight of vegetable oil, 2-20 parts by weight of fish oil, and 0.1-0.5 part by weight of flavor and antioxidants (column 4, lines 5-15). Vegetable oil is selected from corn, peanut, cottonseed, soybean, safflower, and other edible vegetable oils of commerce (column 2, lines 36-42).

Claims 1-3, 6-9, 12 and 13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Schroeder et al. US 4,913,921.

Schroeder discloses a food product comprising 10-25% fish oil derived from salmon, sardine, cod liver, and menhaden oil (column 3, lines 13-61). The composition further comprises vegetable oil, antioxidant and flavor masking agents (column 5, lines 29 through column 6, lines 1-63). Schroeder also teaches the composition additionally comprises vitamins in an amount from about 0.1-4% (column 6, lines 64 through column 7, lines 1-3). The vegetable oil is selected from peanut, soybean, coconut, palm, cottonseed, and sunflower oil (column 5, lines 8-12, and examples). Example 7, discloses 0.27% antioxidant, and 56.4245% Durkex 25 (soybean oil).

It is noted that the cited references do not expressly teach the limitation wherein the palatable viscous carrier protects the ingestible substance from degradation. However, the intended use of the claimed composition does not patentably distinguish the composition, per se. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Furthermore, it is noted that such limitation is inherent because both, Greenberg and Schroeder teach compositions comprising the claimed ingredients that exhibit remarkable stability.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 6-8, 12-16 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derrieu et al. US 6,010,720, in view of Greenberg et al. US 3,745,023.

Derrieu teaches a composition comprising from 35-60% of lipid substances, between 5-45% of at least one palatable substances, and between 0-50% of another suitable additional ingredient (column 2, lines 55-67). The composition is for oral administration of medicaments, such as vitamins, nutritional substances, vaccines and the like (column 1, lines 1-8). The lipid substances are mixtures of vegetable, fish, mineral, semi-synthetic and synthetic oils (column 3, lines 49-61). The palatable substances can be flavoring agents (column 3, lines 65-68). Examples 1 and 5 show the use of vitamins A, D, Bs, and E (tocopherol). Derrieu also teaches the method for

preparing the composition comprises melting the lipid substances, mixing the polymer at the same temperature, cooling the mixtures, and adding bioactive substance and the remainder of the composition (column 4, lines 39-63).

Derrieu does not teach the combination of vegetable oil and fish oil, however, Derrieus' examples show different mixtures of oils, for example fish oil and paraffin.

Greenberg teaches an appetite enhancing composition comprising 25-72 parts by weight of animal fat extracts, 25-72 parts by weight of vegetable oil, 2-20 parts by weight of fish oil, and 0.1-0.5 part by weight of flavor and antioxidants (column 4, lines 5-15). Vegetable oil is selected from corn, peanut, cottonseed, soybean, safflower, and other edible vegetable oils of commerce (column 2, lines 36-42). Thus, it would have been obvious for one of ordinary skill in the art to modify the palatable composition of Derrieu using the mixture of vegetable oil and fish oil in view of the teachings of Greenberg, because the references teach the advantageous results in the use of lipid substances, such as vegetable and marine oils (Derrieu at column 2, lines 21-43; and Greenberg at column 2, lines 15-64). The expected result would be a stable composition suitable for oral administration of medicaments and nutritional substances to animal such as mammals.

Claims 4, 5, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derrieu et al. US 6,010,720 and Greenberg et al. US 3,745,023, in view of Desai et al. US 4,867,986.

Derrieu and Greenberg are relied upon for the reasons stated above. The references do not teach the specific antioxidant, such as β-, α-tocopherol. However, tocopherol is known in pharmaceutical art as an antioxidant. To be more significant, Desai is cited solely for the teaching of antioxidant including d-α-tocopherol and the like (column 5, lines 40-52). Thus, it would have been obvious for one of ordinary skill in the art to use tocopherol as an antioxidant in the composition of Derrieu and Greenberg with the expectation of obtaining a stable composition comprising mixtures of vegetable oil and marine oil.

Claims 17, 18 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derrieu et al. US 6,010,720 and Greenberg et al. US 3,745,023, in view of Gehrman et al. US 4,518,696.

Derrieu and Greenberg are relied upon for the reasons stated above. The references do not teach the claimed probiotic substances, such as microorganisms, however, Derrieu teaches the use of medicaments, vitamins, trace elements, amino acids, nutritional substances, vaccines and the like (column 1, lines 1-8). Gehrman teaches a composition comprising various species of lactobacillus suspended in sunflower oil (abstract, and column 1, lines 55-63). Some or all of the bacteria are potentially useful for probiotic administration to domestic animals (column 2, lines 7-15). Thus, it would have been obvious for one of ordinary skill in the art to use the microorganism in view of the teaching of Gehrman as a medicament, vaccines or the

like in the composition of Derrieu and Greenberg with the expectation of obtaining a stable composition comprising mixtures of vegetable oil and marine oil.

Response to Arguments

Applicant's arguments filed 10/19/04 have been fully considered but they are not persuasive.

Applicant argues that applicant has amended claim 1 as discussed during the interview of August 24, 2004. As such, applicant respectfully requests the Examiner withdraw the 102(b) rejection by Greenberg et al. (US 3,745,023). Contrary to the applicant's argument, during the telephonic interview dated August 24, 2004, applicant's attorney proposed to amend the claims to include "a drug substance" because applicant's attorney alleged that Greenberg is directed to a pet food composition (see Interview Summary). The Interview Summary stated that "If specification provides support for the drug substance limitation [being proposed by applicant's attorney], the 102(b) rejection bye Greenberg will be withdrawn. The amendment dated 10/19/04 has not amended the claims as discussed during the telephonic interview. Accordingly, the 102(b) rejection by Greenberg et al. is maintained.

Applicant argues that Schroeder does not suggest or disclose a viscous carrier as offering any form of protection to an ingestible substance. However, applicant's attention is called to column 9, lines 39-40, where Schroeder discloses the formulation exhibits good stability against fish oil deterioration for up to 16 weeks. Accordingly, it is the position of the examiner that the carrier formulation of Schroeder inherently protects

the ingestible substance from degradation because Schroeder discloses formulation that exhibits remarkable stability throughout his reference.

Applicant argues that Schroeder does not teach the claimed ratios of vegetable oil and fish oil. However, it is noted Schroeder is relied upon for the teachings within the four-wall patent. At claim 30, Schroeder recites about 0.1% to 80% by weight of the food product comprising an oil component. Thus, Schroeder does teach the weight percent of vegetable and fish oils being claimed.

Applicant argues that there is no motivation to combine the Derrieu reference with the Greenberg reference, because Greenberg teaches a food composition for improving taste while Derrieu teaches composition relates to the oral delivery of chemicals and medicaments; and because Derrieu and Greenberg teach two distinct forms of delivery. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*,

837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Greenberg is cited solely for the teaching of mixture of fish oil and vegetable oil such as corn, peanut, cottonseed, soybean, safflower, and other edible vegetable oils of commerce.

In response to applicant's argument that there is no suggestion to combine Derrieu, Greenberg, and Gehrman, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Gehrman is cited solely for the teaching of medicaments can be probiotic substances.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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